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EXAMINER	
MACAULEY, SHERIDAN R	
ART UNIT	**PAPER NUMBER**
1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,671	NISHIO, FUMIHIDE	
	Examiner	Art Unit	
	SHERIDAN R. MACAULEY	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/27/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A response and amendment were received and entered on September 12, 2008. Claims 1-37 are cancelled. New claims 38-57 are pending.

Election/Restrictions

1. Applicant elected with traverse of the invention of claims 1-18 and element (a) as the species of elements, a nonionic surfactant as the species of compounds, combination 1 as the species of combinations, and SEQ ID NO: 1 as the species of peptides in the reply filed on November 5, 2007. The requirement was deemed proper and was made FINAL in the office action mailed on March 19, 2008. Although applicant has cancelled all claims drawn to the non-examined inventions, it is noted that the restriction requirement still applies to the instant claims.

2. Claims 38-57, insofar as they read upon the elected species, are examined in the merits in this office action.

Claim Rejections - 35 USC § 112

3. Rejections under 35 USC 112 have been withdrawn due to applicant's amendment.

Claim Rejections - 35 USC § 102

4. Rejections under 35 USC 102 have been withdrawn due to amendment.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 38-41, 44-46, 49-52 and 54-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kunihiro et al. (US 5,834,028; document cited in previous action) in view of Yui et al. (EP 1029548 A1). The claims recite a method for dissolving soluble thrombomodulin-containing freeze-dried preparation that contains soluble thrombomodulin as an active ingredient, said method comprising: dissolving the freeze-dried preparation in a dissolving aqueous solution in the presence of a nonionic surfactant, at least at the time of the dissolving, to obtain a solution containing soluble thrombomodulin, after the dissolving, at a concentration of 10 mg per milliliter or higher, wherein said method prevents and/or inhibits air bubbles from being contained in the solution at the time of dissolving of said soluble thrombomodulin-containing freeze-dried preparation. The claims further recite that the method prevents and/or inhibits the

generation of air bubbles, specifically minute bubbles, that form at the time of the addition of the dissolving aqueous solution to dissolve the freeze-dried preparation. The claims further recite that the surfactant is present in the dissolving aqueous solution used for dissolving or present in the freeze-dried preparation. The claims further recite that the resulting solution of soluble thrombomodulin has a concentration of 17, 25 or 30 mg per milliliter or more. The claims further recite that the fluid volume of the solution of thrombomodulin is 0.1-2 milliliters and have an osmotic pressure ration upon dissolution of 0.5-2.0. The claims further recite that the soluble thrombomodulin-containing freeze-dried preparation is allowed to contain a combination containing glutamic acid or a salt thereof and mannitol, or that the soluble thrombomodulin-containing freeze-dried preparation is allowed to contain one or two compounds selected from the group consisting of arginine, glutamic acid, proline, serine, glycine, histidine, asparagine, lysine, phenylalanine, and valine, or salts thereof, trehalose, lactose, and sucrose; and that a nonionic surfactant is present in the soluble thrombomodulin-containing freeze-dried preparation and/or in the dissolving aqueous solution for dissolving the soluble thrombomodulin-containing freeze-dried preparation. The claims further recite that the nonionic surfactant comprises at least one compound selected from the group consisting of polyoxyethylene sorbitan fatty acid ester, polyoxyethylene/ polyoxypropylene copolymer, polyoxyethylene alkylether, polyoxyethylene fatty acid ester, and polyoxyethylene hydrogenated castor oil and is present at an amount of 0.01 mg ore more per 10 mg of thrombomodulin. The claims further recite that the soluble composition can be used in for intramuscluar or subcutaneous injection.

8. Kunihiro teaches a method for preparing and reconstituting a lyophilized (i.e. freeze-dried) composition comprising soluble thrombomodulin and a nonionic surfactant (i.e. a surface-active agent), such as a polyoxyethylene sorbitan fatty acid ester (abstract, col. 9, lines 29-52). Kunihiro teaches that the surfactant may be present in the lyophilized preparation or in the solution in which the preparation is dissolved (col. 11, lines 15-36). Kunihiro teaches the preparations of fluids with fluid volumes of 2 milliliters (col. 20, experiment 5). Kunihiro teaches that the lyophilized composition may comprise arginine or lactose and that the composition may be mixed with surfactant (e.g. polysorbate 80) at the claimed concentration (abstract, col. 20, experiment 5). Although the reference teaches the preparation of soluble thrombomodulin solutions at concentrations of up to 5 mg per milliliter (col. 24, example 5), the reference does not specifically teach the preparation of preparations with concentrations of 10 mg per milliliter and greater.

9. Yui teaches the preparation of highly concentrated thrombomodulin preparations, such as solutions at concentrations of 10 to 15 mg per milliliters, and that there is no upper limit on the concentration of the preparations (p. 9, lines 30-33). The reference teaches that the preparations may be used for injection (p. 3, par. 12).

10. A method comprising nearly all of the elements recited in the claims was known at the time of the invention, as taught by Kunihiro. It was further known that highly concentrated soluble thrombomodulin preparations could be made for use in injections, as taught by Yui. One of ordinary skill in the art would have been motivated to combine these teachings to prepare a highly -concentrated thrombomodulin solution using the

methods of Kunihiro because Yui teaches that highly-concentrated preparations of such a solution would have been desirable and could have been prepared with a reasonable expectation of success at the time of the invention. One of ordinary skill in the art would therefore have recognized that a solution as recited in the claims could have been prepared and would have arrived at such a solution in the course of routine experimentation. Furthermore, the method of the prior art would inherently have resulted in the prevention of bubbles and the osmotic pressure recited in the claims. It would therefore have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of the prior art to arrive at the claimed invention.

11. Claims 38-41, 44-47, 49-52 and 54-57 rejected under 35 U.S.C. 103(a) as being unpatentable over Kunihiro et al. (US 5,834,028) in view of Yui et al. (EP 1029548 A1), as applied to claims 38-41, 44-46, 49-52 and 54-57 above, and further in view of JP 11-171790 (see English abstract; document cited in previous action). Claims 38-41, 44-46, 49-52 and 54-57 are discussed above. Claims 47 recites that the soluble thrombomodulin-containing freeze-dried preparation is allowed to contain a combination containing glutamic acid or a salt thereof and mannitol; and that a nonionic surfactant is present in the soluble thrombomodulin-containing freeze-dried preparation and/or in the dissolving aqueous solution for dissolving the soluble thrombomodulin-containing freeze-dried preparation.

12. Kunihiro teaches a method for preparing and reconstituting a lyophilized (i.e. freeze-dried) composition comprising soluble thrombomodulin and a nonionic surfactant

(i.e. a surface-active agent), such as a polyoxyethylene sorbitan fatty acid ester (abstract, col. 9, lines 29-52). Kunihiro teaches that the surfactant may be present in the lyophilized preparation or in the solution in which the preparation is dissolved (col. 11, lines 15-36). Kunihiro teaches the preparations of fluids with fluid volumes of 2 milliliters (col. 20, experiment 5). Kunihiro teaches that the lyophilized composition may comprise arginine or lactose and that the composition may be mixed with surfactant (e.g. polysorbate 80) at the claimed concentration (abstract, col. 20, experiment 5). Although the reference teaches the preparation of soluble thrombomodulin solutions at concentrations of up to 5 mg per milliliter (col. 24, example 5), the reference does not specifically teach the preparation of preparations with concentrations of 10 mg per milliliter and greater.

13. Yui teaches the preparation of highly concentrated thrombomodulin preparations, such as solutions at concentrations of 10 to 15 mg per milliliters, and that there is no upper limit on the concentration of the preparations (p. 9, lines 30-33). The reference teaches that the preparations may be used for injection (p. 3, par. 12).

14. At the time of the invention, it would have been obvious to combine the teachings of Kunihiro and Yiu to arrive at the claimed invention. Although Kunihiro further discloses the use of mannitol as an additive to a thrombomodulin composition (col. 18, lines 5-9), the references do not specifically teach the addition of mannitol and glutamic acid.

15. JP 11-171790 teaches a method for preventing the denaturation of thrombomodulin in a freeze-dried preparation by adding mannitol and glutamic acid (see English abstract).

16. At the time of the invention, a method for preparing thrombomodulin comprising nearly all of the claimed elements was known, as taught by Kunihiro and Yiu. It was further known that mannitol and glutamic acid could be used in a similar method. One of ordinary skill in the art would have been motivated to combine these teachings because Kunihiro teaches the desirability to stabilize a thrombomodulin-containing solution for lyophilization (abstract) and JP 11-171790 teaches that the addition of the claimed components help to prevent denaturation of the thrombomodulin in a method for preparing the dried composition. One of ordinary skill in the art would have had a reasonable expectation of success in combining these teachings because both references disclose that the claimed agents are compatible with methods for preparing dried thrombomodulin-containing compositions. It would therefore have been obvious to one of ordinary skill in the art to combine the teachings discussed above to arrive at the claimed invention.

17. Claims 38-41, 44-46 and 48-57 rejected under 35 U.S.C. 103(a) as being unpatentable over Kunihiro et al. (US 5,834,028) in view of Yui et al. (EP 1029548 A1), as applied to claims 38-41, 44-46, 49-52 and 54-57 above, and further in view of Zushi (US 5,574,4007; document cited in previous action). Claims 38-41, 44-46, 49-52 and 54-57 are discussed above. Claims 48 and 53 recite that: the soluble thrombomodulin-

containing freeze-dried preparation contains (1) urea or (2) urea and an amino acid; and a nonionic surfactant is present in the soluble thrombomodulin-containing freeze-dried preparation and/or in the dissolving aqueous solution for dissolving the soluble thrombomodulin-containing freeze-dried preparation, and that the soluble thrombomodulin comprises a peptide containing the following sequence, has an action of promoting activation of protein C with thrombin, and can be dissolved in the absence of a surfactant: an amino acid sequence at positions 19 to 516 of SEQ ID NO. 1 in a sequence listing.

18. Kunihiro teaches a method for preparing and reconstituting a lyophilized (i.e. freeze-dried) composition comprising soluble thrombomodulin and a nonionic surfactant (i.e. a surface-active agent), such as a polyoxyethylene sorbitan fatty acid ester (abstract, col. 9, lines 29-52). Kunihiro teaches that the surfactant may be present in the lyophilized preparation or in the solution in which the preparation is dissolved (col. 11, lines 15-36). Kunihiro teaches the preparations of fluids with fluid volumes of 2 milliliters (col. 20, experiment 5). Kunihiro teaches that the lyophilized composition may comprise arginine or lactose and that the composition may be mixed with surfactant (e.g. polysorbate 80) at the claimed concentration (abstract, col. 20, experiment 5). Although the reference teaches the preparation of soluble thrombomodulin solutions at concentrations of up to 5 mg per milliliter (col. 24, example 5), the reference does not specifically teach the preparation of preparations with concentrations of 10 mg per milliliter and greater.

19. Yui teaches the preparation of highly concentrated thrombomodulin preparations, such as solutions at concentrations of 10 to 15 mg per milliliters, and that there is no upper limit on the concentration of the preparations (p. 9, lines 30-33). The reference teaches that the preparations may be used for injection (p. 3, par. 12).

20. At the time of the invention, it would have been obvious to combine the teachings of Kunihiro and Yiu to arrive at the claimed invention. However, the references do not specifically teach the use of a thrombomodulin with the claimed sequence in the method or the addition of urea to the composition.

21. Zushi teaches a peptide sequence for thrombomodulin that is identical to the claimed SEQ ID NO:1 (see Alignment 1, included in prior action). Zushi teaches that urea may be added to a peptide solution to in a process for altering intramolecular structure (col. 26, lines 53-67).

22. At the time of the invention, a method for preparing thrombomodulin comprising nearly all of the claimed elements was known, as taught by Kunihiro and Yiu. A thrombomodulin was further known at the time of the invention which comprised the claimed sequence, as taught by Zushi. One of ordinary skill in the art would have been motivated to use the peptide taught by Zushi in the process of Kunihiro because Kunihiro teaches that the method can be used with any thrombomodulin (col. 8, lines 15-25). One of ordinary skill in the art would thus have recognized that the thrombomodulin of Zushi would have been acceptable for use in the method of Kunihiro. One of ordinary skill in the art could have used the thrombomodulin of Zushi in the method of Kunihiro with a reasonable expectation of success because the method of

Kunihiro could be used with any thrombomodulin. Further, one of ordinary skill in the art would have been motivated to add urea to the composition because Zushi teaches that this is desirable in processes using the claimed thrombomodulin. Since Zushi teaches that urea is compatible for use with the thrombomodulin, one would have recognized that urea could be added to a composition comprising the thrombomodulin with a reasonable expectation of success. It would therefore have been obvious to one of ordinary skill in the art to combine the teachings discussed above to arrive at the claimed invention.

23. Claims 38-46, 49-52 and 54-57 rejected under 35 U.S.C. 103(a) as being unpatentable over Kunihiro et al. (US 5,834,028) in view of Yui et al. (EP 1029548 A1), as applied to claims 38-41, 44-46, 49-52 and 54-57 above, and further in view of Klokkers-Bethke et al. (US 5,335,769; document cited in previous action). Claims 38-41, 44-46, 49-52 and 54-57 have been discussed above. Claims 42 and 43 recite that the inner wall of the container to be used in the dissolving step is coated with silicone and that the pressure in the container to be used in dissolving the soluble thrombomodulin-containing freeze-dried preparation is kept at a reduced pressure.

24. Kunihiro teaches a method for preparing and reconstituting a lyophilized (i.e. freeze-dried) composition comprising soluble thrombomodulin and a nonionic surfactant (i.e. a surface-active agent), such as a polyoxyethylene sorbitan fatty acid ester (abstract, col. 9, lines 29-52). Kunihiro teaches that the surfactant may be present in the lyophilized preparation or in the solution in which the preparation is dissolved (col.

11, lines 15-36). Kunihiro teaches the preparations of fluids with fluid volumes of 2 milliliters (col. 20, experiment 5). Kunihiro teaches that the lyophilized composition may comprise arginine or lactose and that the composition may be mixed with surfactant (e.g. polysorbate 80) at the claimed concentration (abstract, col. 20, experiment 5). Although the reference teaches the preparation of soluble thrombomodulin solutions at concentrations of up to 5 mg per milliliter (col. 24, example 5), the reference does not specifically teach the preparation of preparations with concentrations of 10 mg per milliliter and greater.

25. Yui teaches the preparation of highly concentrated thrombomodulin preparations, such as solutions at concentrations of 10 to 15 mg per milliliters, and that there is no upper limit on the concentration of the preparations (p. 9, lines 30-33). The reference teaches that the preparations may be used for injection (p. 3, par. 12).

26. At the time of the invention, it would have been obvious to combine the teachings of Kunihiro and Yiu to arrive at the claimed invention. However, the references do not specifically teach the use of a silicone-coated container for the preparation of a thrombomodulin-containing solution or the maintenance of the container at a reduced pressure.

27. Klokkers-Bethke teaches a glass container that is internally coated with silicone for the preparation of a freeze-dried product (abstract). The reference also teaches the preparation and maintenance of the freeze-dried product at reduced pressure (a vacuum; col. 4, lines 37-50).

28. At the time of the invention, a method for preparing thrombomodulin comprising nearly all of the claimed elements was known, as taught by Kunihiro and Yiu. It was further known that freeze-dried preparations, such as the one taught by Kunihiro, could be prepared and reconsituted in silicone-coated containers and maintained under reduced pressure, as taught by Klokkers-Bethke. One of ordinary skill would have been motivated to use the method and product of Klokkers-Bethke with the method of Kunihiro because Kunihiro discusses the desirability for the prevention of adsorption of peptides such as thrombomodulin (col. 4, lines 42-64) and Klokkers Bethke teaches that the method and container are suitable for use with proteins and peptides (col. 2, lines 45-54). One of ordinary skill in the art would have had a reasonable expectation of success in combining these teachings because the method of Kunihiro could be used with any lyophilization method (col. 11, lines 36-44) and the teachings of Klokkers-Bethke could be used with any medicinal substance (col. 3, lines 23-25). It would therefore have been obvious at the time of the invention to combine the teachings discussed above to arrive at the claimed invention.

29. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Response to Arguments

30. Applicant's arguments filed September 12, 2009 have been fully considered but they are not persuasive. Applicant argues that the cited references do not render

obvious the claimed invention. However, as discussed in the rejections above, the claimed invention is rendered obvious by the prior art. Specifically, applicant argues that the cited references do not teach a soluble thrombomodulin preparation containing 10 mg per milliliter. It is noted, however, that this aspect of applicant's claimed invention is taught by Yui. It would have been obvious to combine Yui with the teachings of the prior art, as discussed above, and thus applicant's argument has not been found to be persuasive. Applicant also argues that the cited references teach away from the instant invention. This is not found to be persuasive, however, because the references teach the preparation of a highly concentrated preparation as claimed. Applicant's argument that Kunihiro does not anticipate a highly concentrated preparation and that this teaches away from the invention of the instant claims is not found to be persuasive because the reference teaches the preparation of solutions containing up to 5 mg thrombomodulin per milliliter, which is close to the range recited in the claims. Yui further teaches that more highly concentrated preparations may be made and provides a reasonable expectation of success in preparing such preparations. Thus, the prior art does not teach away from the invention as claimed. Although applicant also argues that one of ordinary skill in the art practicing the method of the combined prior art would not expect predictable results, it is noted that one of ordinary skill in the art would have been able to produce a highly-concentrated preparation of thrombomodulin using the methods of the prior art because such methods were known in the art at the time of the invention, as discussed in the rejections above.

31. In response to applicant's argument that the teachings of the prior art do not render the claimed invention obvious because they fail to recognize the problem solved by the claimed method (i.e., the reduction in air bubbles in a highly concentrated thrombomodulin solution) and because their objectives vary from the objective of the claimed invention, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Although the references discuss the preparation of a thrombomodulin for improved stability rather than the reduction of bubbles, one of ordinary skill in the art would have arrived at the claimed method using the teachings of the prior art.

32. Therefore, applicant's arguments have been fully considered, but they have not been found to be persuasive.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHERIDAN R. MACAULEY whose telephone number is (571)270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM

/Ruth A. Davis/
Primary Examiner, Art Unit 1651